

AMENDMENTS TO THE SPECIFICATION

Please amend the specification as follows:

- Please replace the paragraph at page 4, line 27 to page 5, line 2 with the following amended paragraph:

C 1
Further, using terbutaline and other β -adrenergic agonists for prevention or treatment of dysmenorrhea or premature labor without the normally-expected side effects has been disclosed in Levine, et al., United States Patent Application Ser. No. 09/145,172 6,126,959. These side effects are discussed further below.

- Please replace the paragraph at page 5, lines 9-24 with the following amended paragraph:

C 2
Additionally, therapeutic uses of terbutaline have produced significant adverse side effects in the patient, as mentioned above, especially with respect to the cardiovascular system. As a sympathomimetic amine, terbutaline can cause problems in patients with cardiovascular disorders, including arrhythmia, coronary insufficiency, and hypertension. Intravenous administration of terbutaline has been associated with palpitations and peripheral tremors. *Åkerlund, M., Andersson, K.F., Ingemarsson, I., Effects of Terbutaline on Myometrial Activity, Uterine Blood Flow and Lower Abdominal Pain in Women With Primary Dysmenorrhea. Br. J. Obstet., Gyncol., 83:673-78 (1976).* In addition, intravenous terbutaline has been reported to aggravate preexisting diabetes and ketoacidosis. Terbutaline also may be problematic for patients with hyperthyroidism, diabetes mellitus, or a history of seizures. Other adverse events include tremors, nervousness, increased heart rate, and dizziness. Less frequent adverse effects include headaches, drowsiness, vomiting, nausea, sweating, muscle cramps, and ECG changes. Thus, despite its efficacy, such treatments are often contra-indicated due to the potential adverse consequences – except when administered as discussed in United States Patent Application Ser. No. 09/145,172 6,126,959, cited above.

- Please replace the paragraph at page 9, line 28 to page 10, line 2 with the following amended paragraph:

C3

Polycarbophil has been used in other drug delivery systems. For example, polycarbophil is a main ingredient in the REPLENS® brand vaginal moisturizer Replens®. It has also been used as a base for compositions with other active substances such as progesterone (Crinone® CRINONE® brand topical progesterone preparation) (see U.S. Pat. No. 5,543,150) and Nonoxynol-9 (Advantage-S® ADVANTAGE-S® brand contraceptive gel) (see U.S. Pat. No. 5,667,492).

- Please replace the paragraph at page 12, lines 15-25, with the following amended paragraph:

C4

General preparation involves hydration of the polymers, separating separate mixing of the polymer phase (water-soluble ingredients) and the oil phase (oil-soluble ingredients), heating and mixing of the two phases, and homogenization of the mixture. As an example, the polymer phase may be prepared by dissolving sorbic acid and methylparaben in purified water (which should contain approximately 3% of excess volume to account for evaporative losses), preferably at 75°-78°C. The mixture is then cooled generally to room temperature, and the polycarbophil and Carbomer 934P are added to the mixture. The polymers are hydrated by mixing for several hours, generally about 2-3 hours until a uniform, smooth, homogenous, lump-free, gel-like polymer mixture is obtained. When the polymers are completely hydrated, the [[\square -adrenergic]] β -adrenergic agonist is added and mixed in, until a homogeneous suspension is obtained.